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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/16/2001

Joseph J. Chang

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WOOD, HERRON AND EVANS
2700 CAREW TOWER
CINCINNATI, OH 45202

EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

12/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/978,457	Applicant(s) CHANG, JOSEPH J.	
	Examiner THEODORE J. STIGELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, and 15-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Luther (4,964,854). Luther discloses a needle cannula (26) having a distal point, a proximal end and further having a shaft with a circumference, a tip protector (40) having a base, the tip protector defining an opening to receive the needle cannula shaft and the tip protector is slideably mounted thereon, blocking means (50, 54) coupled to the tip protector for blocking the tip protector opening so as to enclose the distal point of the needle cannula within the tip protector, a gasket (60) coupled to the tip protector base defining an opening of a size to receive the needle cannula shaft,

Art Unit: 3763

impeding means (29) fixedly coupled to the needle cannula shaft at a predetermined location of the shaft for impeding movement of the tip protector along the needle cannula shaft beyond a pre determined distance from the needle cannula distal point, further comprising a flash chamber (36) coupled to the needle cannula at the needle cannula proximal end, wherein the blocking means comprises a tab (50, 54) having a length sufficient to block the tip protector opening, the tab pivotably coupled to the tip protector within the tip protector opening and slideably engaging the needle cannula shaft in a first biased position such that upon removal of the needle cannula shaft the tab is free to pivot to a second position extending across the tip protector opening, wherein the impeding means comprises an irregularity in the needle cannula shaft circumference a pre-determined distance from the needle cannula distal point occluding passing of the needle cannula shaft through the gasket opening.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 10-11, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luther (4,964,854). Luther discloses the claimed invention except for teaching that the tabs are made of metal and the tip protector is made of a transparent material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use these materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 1-11 and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crawford et al. (5,601,536) in view of Chang et al. (5,419,766). See at least the embodiment shown in Figures 11-14. Crawford discloses an apparatus comprising a needle cannula (12) having a point (16), a tip protector (11) having a base (21), blocking means (18,19) coupled to the tip protector for blocking an opening of the tip protector so as to enclose the point of the needle, impeding means (22, 26) fixedly coupled to the needle cannula for impeding movement of the tip protector beyond a predetermined distance from the point, further comprising a flash chamber (40), and wherein the blocking means includes a biased tab and the impeding means includes an irregularity in the needle shaft. Crawford does not disclose a gasket coupled to the tip protector base.

Chang discloses a similar assembly wherein the base of the tip protector (11) includes a gasket (16). Chang teaches that the gasket is useful in preventing backflow along the needle and also wipes blood from the distal end of the needle as the needle is withdrawn from the catheter assembly. One of ordinary skill would understand that this feature is desirable because it lessens the chance for the physician of contact with the patient's blood.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Crawford with the gasket of Chang in order to provide a tip protector that prevents backflow and has a blood wiping capability.

Response to Arguments

Applicant's arguments see Remarks, filed 9/15/2008, with respect to the combination of Jagger ('692) and Chang ('766) have been fully considered and are persuasive. The rejection has been withdrawn.

Applicant's arguments in view of Luther (4,964,854) filed 2/14/2008 have been fully considered but they are not persuasive.

Luther 4,964,854

In response to the applicant's argument that Luther does not disclose a gasket defining an opening nominally of a size almost identical to the shaft circumference and through which the needle shaft is movable, the examiner respectfully disagrees. The examiner still maintains that element (60) provides a sealing capability with annular ring (62) and can therefore be considered a gasket. The examiner maintains that the new limitations are broad and that the circumference of element (60) at the distal end is

almost identical to the needle shaft. The examiner acknowledges that element (60) does not provide a fluid tight seal around the needle shaft and that such a limitation would surely overcome the Luther reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/

Application/Control Number: 09/978,457

Page 7

Art Unit: 3763

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763